

### REMARKS

Upon entry of this amendment, claims 1, 3, and 9-29 are pending in the application. Claims 2, 4-8, and 30-60 are canceled. Claims 30-60 are canceled for being drawn to a non-elected invention. Claims 1, 3, 9, 10, 17, 19, and 25 are amended. Support for the amendment to claim 1 can be found at least in original claims 2 and 5. Claims 3, 9, and 10 are amended to correct claim dependency. Claim 17, 19, and 25 are amended to correct a typographical errors. No new matter is added.

#### Claim Objections

Claims 5 and 6 are objected to for reciting that the “administration is administered”. *See*, Office Action at page 2. Claims 5 and 6 are canceled. This rejection is moot and should be withdrawn.

Claim 25 is objected to for reciting “epigallocatechingailate”. *See*, Office Action at page 3. Claim 25 is amended to recite “epigallocatechin gallate”, as requested by the Examiner. Applicants request reconsideration and withdrawal of this rejection.

#### 35 U.S.C. § 102 Rejections

Claims 1-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 2000-344602 to Jiyoukiyuu (“Jiyoukiyuu”). *See*, Office Action at page 3. According to the Examiner, Jiyoukiyuu describes a composition comprising a polyphenol, such as a catechin, for use in organ, tissue, or cell preservation. Applicants respectfully disagree with the foregoing rejection on the grounds that Jiyoukiyuu fails to describe or suggest each and every element of the claimed invention, as amended.

Claim 1, from which the remaining claims subject to the rejection depend, is amended to recite a pharmaceutical composition for protecting and preserving an organ, a tissue, or a cell, comprising a purified polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion, wherein the composition is administered daily at a time from at least two weeks before an operation to the date of the operation.

Jiyoukiyuu does not describe or suggest, expressly or inherently, a pharmaceutical composition for protecting and preserving an organ, a tissue, or a cell, comprising a purified

polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion, wherein the composition is administered daily at a time from at least two weeks before an operation to the date of the operation.

Therefore, Applicants respectfully submit that, contrary to the Examiner's assertions, Jiyoukiyuu fails to describe or suggest each and every element of the claimed invention expressly and/or inherently and, thus, Jiyoukiyuu fails to anticipate the claimed invention. For the foregoing reasons, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Claims 1-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 02/01952 A1 ("the '952 application"). *See*, Office Action at page 4. According to the Examiner, the '952 application describes a composition comprising a polyphenol, such as a catechin, for use in tissue or cell preservation. Applicants respectfully disagree with the foregoing rejection on the grounds that the '952 application fails to describe or suggest each and every element of the claimed invention, as amended.

As stated above, claim 1, from which the remaining claims subject to the rejection depend, is amended to recite a pharmaceutical composition for protecting and preserving an organ, a tissue, or a cell, comprising a purified polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion, wherein the composition is administered daily at a time from at least two weeks before an operation to the date of the operation.

The '952 application does not describe or suggest, expressly or inherently, a pharmaceutical composition for protecting and preserving an organ, a tissue, or a cell, comprising a purified polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion, wherein the composition is administered daily at a time from at least two weeks before an operation to the date of the operation.

Therefore, Applicants respectfully submit that, contrary to the Examiner's assertions, the '952 application fails to describe or suggest each and every element of the claimed invention expressly and/or inherently and, thus, the '952 application fails to anticipate the claimed

invention. For the foregoing reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 1-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,686,082 to N'Guyen ("N'Guyen"). *See*, Office Action at page 5. According to the Examiner, N'Guyen describes a pharmaceutical composition containing a combination of a polyphenol, such as a catechin (*e.g.*, epigallocatechin), and a ginkgo extract, for use in protecting and preserving an organ, tissue, or a cell. Applicants respectfully disagree with the foregoing rejection on the grounds that N'Guyen fails to describe or suggest each and every element of the claimed invention, as amended.

As stated above, claim 1, from which the remaining claims subject to the rejection depend, is amended to recite, in relevant part, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

N'Guyen does not describe or suggest, expressly or inherently, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

Therefore, Applicants respectfully submit that, contrary to the Examiner's assertions, N'Guyen fails to describe or suggest each and every element of the claimed invention expressly and/or inherently and, thus, N'Guyen fails to anticipate the claimed invention. For the foregoing reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 1-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,319,523 to Zhou ("Zhou"). *See*, Office Action at page 5. The Examiner states that Zhou describes a composition comprising a polyphenol derivative, such as a catechin, derived from various botanical sources. Applicants respectfully disagree with the foregoing rejection on the grounds that Zhou fails to describe or suggest each and every element of the claimed invention, as amended.

As stated above, claim 1, from which the remaining claims subject to the rejection depend, is amended to recite, in relevant part, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

Zhou does not describe or suggest, expressly or inherently, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

Therefore, Applicants respectfully submit that, contrary to the Examiner's assertions, Zhou fails to describe or suggest each and every element of the claimed invention expressly and/or inherently and, thus, Zhou fails to anticipate the claimed invention. For the foregoing reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 1-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,242,005 to Legrand ("Legrand"). *See*, Office Action at page 6. The Examiner contends that Legrand describes a composition for protecting and preserving an organ, a tissue, or a cell comprising solid material extracted from crushed grapes, wherein the extract contains a catechin. Applicants respectfully disagree with the foregoing rejection on the grounds that Legrand fails to describe or suggest each and every element of the claimed invention, as amended.

As stated above, claim 1, from which the remaining claims subject to the rejection depend, is amended to recite, in relevant part, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

Legrand does not describe or suggest, expressly or inherently, a composition comprising a polyphenol or a purified mixture of polyphenols in an amount sufficient for preservation of the organ, tissue, or cell during ischemia or reperfusion.

Therefore, Applicants respectfully submit that, contrary to the Examiner's assertions, Legrand fails to describe or suggest each and every element of the claimed invention expressly and/or inherently and, thus, Legrand fails to anticipate the claimed invention. For the foregoing reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

**Double Patenting Rejections**

Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 11/418,421.

Applicants disagree. However, in the interest of expediting prosecution of the present application, Applicants file herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c). Withdrawal of this rejection is respectfully requested.

### CONCLUSION

In view of the aforementioned remarks and amendments, the Applicants believe that each of the pending claims is in condition for allowance. Reconsideration, withdrawal of the rejections, and passage of the case to issue is respectfully requested. A notice to this effect is earnestly solicited.

If, upon receipt and review of this amendment, the Examiner believes that the present application is not in condition for allowance and that changes can be suggested which would place the claims in allowable form, the Examiner is respectfully requested to call Applicants' undersigned counsel at the number provided below.

Respectfully submitted,

Date: August 22, 2008

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